



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/193,538	11/17/1998	PATRICIA A. BILLING-MEDEL	6193.US.P1	2144

23492 7590 12/05/2001

ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK, IL 60064-6050

EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
----------	--------------

1655

DATE MAILED: 12/05/2001

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/193,538

Applicant(s)

Billing-Medel et al

Examiner

Jehanne Souaya

Art Unit

1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-37, 39, 40, 42-44, and 50-78 is/are pending in the application.
- 4a) Of the above, claim(s) 23-37, 39, 40, 42-44, 50, and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

Art Unit: 1655

DETAILED ACTION

Continued Prosecution Application

1. The request filed on September 17, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/193,538 is acceptable and a CPA has been established. An action on the CPA follows.

2. Currently, claims 23-37, 39-40, 42-44, and 50-78 are pending in the instant application. Claims 23-37, 39-40, 42-44, and 50-51 are withdrawn from consideration as being directed to non elected subject matter from a previous restriction requirement. Claims 52-78 are currently under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is NON-FINAL.

Art Unit: 1655

Maintained Rejections

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from <http://www.uspto.gov/web/menu/utility.pdf>]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests (see below).

"Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility."

Art Unit: 1655

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute. See also the MPEP at 2107 - 2107.02.

4. Claims 52-78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific or substantial asserted utility, or a well established utility.

The claims are drawn to polynucleotides having a sequence selected from the group consisting of SEQ ID NOS 1-7, to methods of detecting a target polynucleotide using the polynucleotides of SEQ ID NOS 1-7, and to kits comprising these polynucleotides.

The specification teaches the general utility for the invention is detection of the gene product itself in a sample (p. 10 of the specification). This is not deemed to be specific as this utility is applicable to polynucleotides in general. The specification asserts that the polynucleotides of the invention can be used to detect, amplify, or quantify genes, nucleic acids, cDNAs or mRNAs relating to breast tissue disease and conditions associated therewith (p. 25).

Art Unit: 1655

The specification further asserts that the compositions and methods described in the specification will enable the identification of certain markers as indicative of breast tissue disease or condition wherein this information will aid in, for example, detecting conditions associated with BS274, especially breast cancer (p. 10-11, bridging paragraph). However this is assertion is not deemed to be substantial as the specification does not teach the specific role of BS274 in breast cancer, nor has the specification demonstrated that BS274 is a marker for breast disease, especially breast cancer. From the teachings in the specification, it is evident that neither the function nor the role of BS274 in association with breast disease or breast cancer was known at the time the invention was filed. At page, 11, lines 6-12, the specification states "It is also *thought* that the polynucleotides or polypeptides and protein encoded by the BS274 gene are useful as a marker. This marker is either elevated in disease such as breast cancer, altered in disease such as breast cancer, or present as a normal protein but appearing in an inappropriate body compartment." The specification only teaches that the BS274 consensus sequence was found more than 28 more times in breast tissue libraries than non breast tissue libraries (p 54), but does not demonstrate that BS274 is a marker for breast cancer (analysis to follow). Therefore, while the BS274 consensus sequence is found to be present to a greater extent in breast tissue, this is not considered a "real world" use for the claimed polynucleotides, kits, or methods of using the polynucleotides of the claimed invention. Further experimentation would be required to determine whether the elevated presence of the BS274 consensus sequence, whether the presence of altered BS274, or whether the presence of BS274 in an inappropriate body compartment is

Art Unit: 1655

indicative of breast disease or breast cancer. The specification also does not provide any teachings as to the function of the protein encoded by BS274.

At page 54, the specification teaches that ESTs were derived from cDNA libraries made from breast tumor tissues, breast non-tumor tissues and numerous other tissues, both tumor and non tumor and entered into a database. The specification teaches that the transcript images were evaluated to identify ESTs that were representative primarily of breast tissue libraries, and that these ESTs were ranked, giving an EST corresponding to the consensus sequence of BS274 (SEQ ID NO 7) which was found in 23% of breast tissue libraries (p. 62). The specification teaches that the consensus sequence (SEQ ID NO 7) or fragments thereof (SEQ ID NOS 1-6) were found more than 28 more times in breast than non breast tissues. However, while the consensus sequence expression appears to be more prevalent in breast tissue, the specification has not demonstrated that BS274 is specific for breast tumor tissue. The specification only teaches that the BS274 consensus sequence was found 28 more times in breast than non breast libraries, but does not teach the ratio of BS274 in normal breast vs. breast tumor tissues. Thus while the specification *suggests* that SEQ ID NOS 1-7 can be used to detect nucleic acids relating to breast tissue disease the specification does not demonstrate such. Furthermore, at page 62, the specification teaches upon hybridization with a BS274 probe, northern analysis revealed an approximately 860 nucleotide band in the RNA of 5 out of 5 normal breast tissue samples was found. While the specification also teaches that the band was found in 2 of 2 breast cancer tissue samples, the specification does not teach whether a difference in expression levels was found

Art Unit: 1655

between breast cancer tissue and non breast tissue. Thus while the specification *suggests* that SEQ ID NOS 1-7 can be used to detect nucleic acids relating to breast tissue disease the specification does not demonstrate such.

Response to Arguments

5. The response traverses the rejection. Applicant submitted a gel that showed strong expression of BS274 in breast tumor tissue and breast cancer cell line T47D. The gel shows faint bands in lanes which are colon tumor, lung tumor, and ovary tumor. The response asserts that these results illustrate the unregulation of BS274 in breast tumors and supports the utility of BS274 as a tumor cell detection marker. This argument has been thoroughly reviewed but was found unpersuasive. The gel submitted by applicant's illustrates that a BS274 is expressed more strongly in breast tumor tissue and a breast cancer cell line over other cancers, the gel however does not provide any information as to the expression level of BS274 in breast tumor vs normal breast tissue. Given this lack of information and given the lack of teachings in the specification as to such a utility, the submission is not found persuasive to indicate that BS274 is a breast tumor marker. The specification only teaches that BS274 consensus sequence was found to be expressed 28 times more in breast tissue than other tissue. The specification, however, does not teach the expression levels of BS274 in normal breast tissue vs breast tumor tissue or tissue that indicates breast disease. A search of the nucleic acid sequences of SEQ ID NOS 1-7 revealed that SEQ ID NO 7 is partially identical to SEQ ID NO 107 taught by Yuqiu et al (WO 00/78960)

Art Unit: 1655

(see also "Result no. 3" from sequence search). Yuqiu teaches that sequences in table 3 (where SEQ ID NO 17 can be found) represent clones with an expression ratio greater than 2 in the level of breast tumor cDNA vs. normal breast cDNA (p. 97). However, Yuqiu does not teach the significance of such values. Furthermore, Yuqiu does not teach whether these results were only found in a single library or whether such results were found in different breast tumor libraries, nor does Yuqiu teach a study that demonstrates that SEQ ID NO 107 can be used as a breast tumor marker. Additionally, SEQ ID NO 107 of Yuqiu does not represent the full length sequence of SEQ ID NO 7 of the present invention, and the two sequences contain several mismatched nucleotides, thus it cannot be determined if SEQ ID NO 107 of Yuqiu is an aberrant form of SEQ ID NO 7 of the presently claimed invention. Yuqiu also does not teach the function of the sequence of SEQ ID NO 107 in breast cancer, or the function of an encoded protein that might elucidate the role of SEQ ID NO 107 as a breast cancer marker. Therefore, the art does not provide a "well established" utility for the sequences of SEQ ID NO 1-7 as a breast tumor detection marker. For these reasons and the reasons made above, and in previous actions, the rejection is maintained.

Claim Rejections - 35 USC § 112

Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

Art Unit: 1655

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-78 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The specification teaches that the compositions and methods described herein will enable the identification of certain markers as indicative of a breast tissue disease or condition, and that the information obtained therefrom will aid in the detecting, diagnosing, staging, monitoring, prognosis, in vivo imaging, preventing or treating diseases of the breast, however the specification does not teach having done so. However, it cannot be determined from the teachings in the specification, and the art is silent as to, what the biological function of the polypeptides encoded by the sequences of SEQ ID NOS 1-7 and also as to how these polynucleotides or polypeptides are correlated to or would be useful in detecting any breast tissue diseases. Therefore, the skilled artisan would have to perform undue experimentation to determine the function of the polypeptides encoded by the sequences of SEQ ID NOS 1-7 or to determine whether the presence of these polynucleotides is associated with breast cancer or any breast disease.

Response to Arguments

7. This rejection is maintained for the reasons set forth in section 5 above.

Art Unit: 1655

New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. Claims 55, 59, and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting a target polynucleotide using reagent polynucleotides selected from the group consisting of SEQ ID NOS 1-7 as primers and probes, does not reasonably provide enablement for methods of detecting a target polynucleotide using reagent polynucleotides selected from the group consisting of SEQ ID NOS 1-7 as primers and probes wherein the presence of a target polynucleotide is indicative of breast disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification does not defines the term "breast disease" (p. 18) as including but not limited to atypical hyperplasia, fibroadenoma, cystic breast disease and breast cancer. However, neither the specification nor the art provide the skilled artisan with enough guidance to practice the invention without undue experimentation.

The specification teaches that transcript images were evaluated to identify ESTs that were representative primarily of breast tissue libraries, and that these ESTs were ranked, giving an EST corresponding to the consensus sequence of BS274 (SEQ ID NO 7) which was found in 23% of breast tissue libraries (p. 54). The specification teaches that the consensus sequence (SEQ ID NO 5) or fragments thereof (SEQ ID NOS 1-6) were found more than 28 more times in breast than non breast tissues. However, while the consensus sequence expression appears to be more

Art Unit: 1655

prevalent in breast tissue, the specification has not demonstrated that BS274 is specific for breast tumor tissue. The specification only teaches that the BS274 consensus sequence was found 28 more times in breast than non breast libraries, but does not teach the ratio of BS274 in normal breast vs. breast tumor tissues or any breast disease tissues. Thus while the specification *suggests* that SEQ ID NOS 1-7 can be used to detect nucleic acids relating to breast tissue disease the specification does not demonstrate such. Furthermore, at page 62, the specification teaches upon hybridization with a BS274 probe, northern analysis revealed an approximately 860 nucleotide band in the RNA of 5 out of 5 normal breast tissue samples was found. While the specification also teaches that the band was found in 2 of 2 breast cancer tissue samples, the specification does not teach whether a difference in expression levels was found between breast cancer tissue and non breast tissue. In addition, the specification does not provide any teachings as to the function of the protein encoded by BS274. Furthermore, "breast disease" is a broad term and is not limited to breast cancer, however the only diseased breast tissue analyzed in the specification was breast tumor tissue.

A search of the nucleic acid sequences of SEQ ID NOS 1-7 revealed that SEQ ID NO 7 is partially identical to SEQ ID NO 107 taught by Yuqiu et al (WO 00/78960) (see also "Result no. 3" from sequence search). Yuqiu teaches that sequences in table 3 (where SEQ ID NO 17 can be found) represent clones with an expression ratio greater than 2 in the level of breast tumor cDNA vs. normal breast cDNA (p. 97). However, Yuqiu does not teach the significance of such values. Furthermore, Yuqiu does not teach whether these results were only found in a single

Art Unit: 1655

library or whether such results were found in different breast tumor libraries, nor does Yuqiu teach a study that demonstrates that SEQ ID NO 107 can be used as a breast tumor marker. Additionally, SEQ ID NO 107 of Yuqiu does not represent the full length sequence of SEQ ID NO 7 of the present invention, and the two sequences contain several mismatched nucleotides, thus it cannot be determined if SEQ ID NO 107 of Yuqiu is an aberrant form of SEQ ID NO 7 of the presently claimed invention. Yuqiu also does not teach the function of the sequence of SEQ ID NO 107 in breast cancer, or the function of an encoded protein that might elucidate the role of SEQ ID NO 107 as a breast cancer marker.

To practice the invention as broadly as it is claimed, the skilled artisan would have to screen a large number of affected and unaffected subjects to determine if one could diagnose breast cancer or any hypertrophic proliferation of breast tissue based on the presence of BS274. Such experimentation is unpredictable given that the specification provides no guidance as to the level of BS274 expression or the presence of altered BS274 in normal breast tissue vs breast tumor tissue, or the whether elevated or aberrant BS274 expression was detected in any breast disease. While the amount of experimentation required is not in and of itself undue, correlating the presence of SEQ ID NOS 1-7 with breast disease is unpredictable given the teachings in the specification of the presence of BS274 polynucleotides in non breast tissue. The specification merely provides the skilled artisan with an invitation to experiment, the carrying out of which would require trial and error, and the results of which are unpredictable, constituting undue experimentation.

Art Unit: 1655

Written Description

9. Claims 52-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 52-74 are drawn to polynucleotides having a sequence selected from the group consisting of SEQ ID NOS 1-7, to methods of detecting a target polynucleotide using the polynucleotides of SEQ ID NOS 1-7, and to kits comprising these polynucleotides. As the specification has not made clear that the term "having" is 'closed', the examiner interprets this term to be "open" terminology. Thus the claims read on sequences that have any number of sequences of the claimed SEQ ID NOS. Likewise, the recitation of "the polynucleotide comprises DNA having a sequence..." in claim 75 is "open" terminology and thus reads on sequences having any number of sequences on either side of the claimed SEQ ID NOS. Claims 76 and 77 are drawn to a nucleic acid sequence that includes an open reading frame operably linked to a control sequence wherein the nucleic acid sequence is selected from the group consisting of SEQ ID NOS 1-7 and to cells transfected with such recombinant systems. This broadly encompasses full genes, genomic sequences, homologs and allelic variants of SEQ ID NOS 1-6 from any source. The specification teaches that SEQ ID NOS 1-6 are fragments of SEQ ID NO 7 which encodes the protein of SEQ ID NO 70 (see fig. 1). Thus, a nucleic acid sequence that includes an open reading frame is considered "open terminology" such that any

Art Unit: 1655

sequences can be present on either side of the polynucleotides of SEQ ID NOS 1-6 such that the resulting nucleic acid sequence possesses an open reading frame. The specification has only taught one open reading frame (included in SEQ ID NOS 7 which encodes SEQ ID NO 17), which is not representative of the large number of homologs and allelic variants encompassed by the broadly claimed invention. There is substantial variability among the species of nucleic acids encompassed by the broad scope of the claims. The specification does not define any structural or functional features of the polynucleotides of SEQ ID NOS 1-7 of the proteins encoded by these polynucleotides that constitutes a substantial portion of the genus. From the lack of description in the specification, the skilled artisan would not be able to envision the large number of sequences that are encompassed by the broadly claimed genus of open reading frames. Furthermore, with regard to claims 55, 59, and 64, the specification fails to teach how these polynucleotides are involved in breast tissue disease and does not demonstrate that the detection of a target polynucleotide using SEQ ID NOS 1-7 is indicative of any breast disease.

Claims 71 and 78 are drawn to polynucleotides selected from the group consisting of SEQ ID NOS 1-7, full complements thereof and equivalent degenerate coding sequences thereof wherein the polynucleotide comprises a sequence encoding at least one epitope and cells transfected with such polynucleotides. The specification defines the term epitope to mean "an antigenic determinant of a polypeptide or protein which can comprise 3 amino acids in a spatial conformation which is unique to the epitope". The specification, however has not taught what regions of the proteins encoded by SEQ ID NOS 1-7 are antigenic and capable of eliciting an

Art Unit: 1655

immune response. The specification teaches that methods of examining spatial conformation are known in the art. However, this does not remedy the lack of written description in the specification as the specification does not teach any structural or functional features of the proteins encoded by SEQ ID NOS 1-7 or which regions would be capable of eliciting an immune response. The art does not remedy the deficiencies in the specification as the art does not teach epitopes of SEQ ID NOS 1-7. From the lack of description in the specification, the skilled artisan would not be able to envision the large number of sequences that are encompassed by the broadly claimed genus of epitopes.

Each of the claimed inventions is a genus for which a representative number of species must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of epitopes encoded by SEQ ID NO 1-7 or sequences that include an open reading frame, the specification fails to show that applicant was in fact "in possession of the claimed invention" at the time the application for patent was filed.

Art Unit: 1655

Conclusion

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya

Patent examiner

Art Unit 1655

Nov. 30, 2001